

**CERTIFICATION OF COMPLIANCE AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ARTHUR J. BREGOLI, JR., M.D.**

I. PREAMBLE

Arthur J. Bregoli, Jr., M.D. (Dr. Bregoli) hereby enters into this Certification of Compliance Agreement (CCA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS). Contemporaneously with this CCA, Dr. Bregoli is entering into a Settlement Agreement with the United States, and this CCA is incorporated by reference into the Settlement Agreement.

The effective date of this CCA shall be the date on which the final signatory of this CCA executes this CCA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

II. INTEGRITY REQUIREMENTS

Dr. Bregoli shall, for a period of three years after the Effective Date of this CCA:

A. Continued Implementation of Compliance Program. Dr. Bregoli shall continue to implement his Compliance Program, as described in the attached Declaration (which is incorporated by reference as Appendix A), and continue to provide, at a minimum, the same level of resources currently provided, throughout this three-year time period. Dr. Bregoli may amend his Compliance Program as he deems necessary, so long as those amendments are consistent with the overall objective of ensuring compliance with the requirements of Medicare, Medicaid, and all other Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f).

B. Reporting of Overpayments. Dr. Bregoli shall promptly refund to the appropriate Federal health care program payor any identified Overpayment(s). For purposes of this CCA, an "Overpayment" shall mean the amount of money Dr. Bregoli has received in excess of the amount due and payable under any Federal health care program requirements. If, at any time, Dr. Bregoli identifies or learns of any Overpayment, Dr. Bregoli shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the

Overpayment from recurring. Also, within 30 days after identification of the Overpayment, Dr. Bregoli shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, Dr. Bregoli shall notify the payor of his efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies and, for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as Appendix B to this CCA. Notwithstanding the above, notification and repayment of any Overpayment amount that is routinely reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

C. Reportable Events. Dr. Bregoli shall report to OIG in writing within 30 days after making a determination (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) that there is a Reportable Event, which shall mean anything that involves: (1) a substantial Overpayment, or (2) a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized. In such report, Dr. Bregoli shall include the following information:

1. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section II.B, and shall include all of the information on the Overpayment Refund Form, as well as:
 - a. the payor's name, address, and contact person to whom the Overpayment was sent; and
 - b. the date of the check and identification number (or electronic transaction number) by which the Overpayment was repaid/refunded;
2. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
3. a description of Dr. Bregoli's actions taken to correct the Reportable Event; and
4. any further steps Dr. Bregoli plans to take to address the Reportable Event and prevent it from recurring.

D. Notification of Government Investigation or Legal Proceedings. Within 30 days after discovery, Dr. Bregoli shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Dr. Bregoli conducted or brought by a governmental entity or its agents involving an allegation that Dr. Bregoli has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Dr. Bregoli shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

E. Annual Reporting Requirements. Dr. Bregoli shall submit to OIG annually a report that sets forth the following information for each Reporting Period (Annual Report):

1. A description of any material amendments to his Compliance Program and the reasons for such changes;
2. Any changes to the level of resources dedicated to his Compliance Program and the reasons for such changes;
3. A summary of all internal or external reviews, audits, or analyses of his Compliance Program (including, at a minimum, the objective of the review, audit, or analysis; the protocol or methodology for the review, audit, or analysis; and the results of the review, audit, or analysis) and any corrective action plans developed in response to such reviews, audits, or analyses;
4. A summary of all internal or external reviews, audits, or analyses related to claims submitted to Federal health care programs (including, at a minimum, the objective of the review, audit, or analysis; the protocol or methodology for the review, audit, or analysis; and the results of the review, audit, or analysis) and any corrective action plans developed in response to such reviews, audits, or analyses;
5. A description of the training, if any, received by Medical Data Services covering the topics identified in Paragraph 5 of the Declaration attached hereto as Appendix A;
6. A report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each state separately, if applicable), and other Federal

health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report; and

7. A certification by Dr. Bregoli that: (a) to the best of his knowledge, except as otherwise described in the Annual Report, Dr. Bregoli is in compliance with the requirements of this Section II and the obligations set forth in the Declaration attached hereto as Appendix A; and (b) he has reviewed the Annual Report and has made reasonable inquiry regarding its content and believes that the information in the Annual Report is accurate and truthful.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

F. Notifications and Submission of Annual Reports. Unless otherwise specified in writing after the Effective Date, all notifications and Annual Reports required under this CCA shall be submitted to the following addresses:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202-619-2078
Facsimile: 202-205-0604

Dr. Bregoli:

Arthur J. Bregoli, Jr., M.D., P.C.
116 Monatiquot Avenue
Braintree, MA 02184
Telephone: 781-848-7242
Facsimile: 781-356-5146

With a copy to:

Michael Kendall, Esq.
McDermott, Will & Emery LLC
28 State Street
Boston, MA 02109
Telephone: 617-535-4085
Facsimile: 617-535-3800

Unless otherwise specified, all notifications and reports required by this CCA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such report or notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

G. OIG Inspection, Audit, and Review Rights. In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Dr. Bregoli's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Dr. Bregoli's locations for the purpose of verifying and evaluating: (a) Dr. Bregoli's compliance with the terms of this CCA; and (b) Dr. Bregoli's compliance with the requirements of the Federal health care programs in which he participates. The documentation described above shall be made available by Dr. Bregoli to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Dr. Bregoli's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Dr. Bregoli shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Dr. Bregoli's employees may elect to be interviewed with or without a representative of Dr. Bregoli present.

H. Document and Record Retention. Dr. Bregoli shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CCA, for four years (or longer if otherwise required by law).

III. BREACH AND DEFAULT PROVISIONS

Dr. Bregoli is expected to fully and timely comply with all of the Integrity Requirements set forth in this CCA.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Dr. Bregoli and OIG hereby agree that failure to comply with the Integrity Requirements set forth in this CCA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$750 (which shall begin to accrue on the day after the date the obligation became due) for each day Dr. Bregoli fails to establish and implement any of the following compliance program elements as described in Section II and the Declaration attached to this CCA as Appendix A:

- a. a Compliance Contact;
- b. a written Code of Conduct;
- c. written Policies and Procedures;
- d. the annual training of Dr. Bregoli and all co-owners, officers, directors and employees;
- e. retention of an outside auditor who performs annual claims reviews to monitor Dr. Bregoli's compliance with Federal health care program requirements;
- f. a Disclosure Program;
- g. Ineligible Persons screening and removal requirements; and
- h. notification of government investigations and legal proceedings.

2. A Stipulated Penalty of \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Dr. Bregoli fails to submit the Annual Reports to OIG in accordance with the requirements of Section II.E by the stated deadlines for submission.

3. A Stipulated Penalty of \$750 for each day Dr. Bregoli fails to grant access to the information or documentation as required in Section II.G of this CCA. (This Stipulated Penalty shall begin to accrue on the date Dr. Bregoli fails to grant access.)

4. A Stipulated Penalty of \$5,000 for each false certification submitted by
Certification of Compliance Agreement

or on behalf of Dr. Bregoli as part of his Annual Reports or otherwise required by this CCA.

5. A Stipulated Penalty of \$750 for each day Dr. Bregoli fails to comply fully and adequately with any Integrity Requirements of this CCA. OIG shall provide notice to Dr. Bregoli, stating the specific grounds for its determination that Dr. Bregoli has failed to comply fully and adequately with the Integrity Requirement(s) at issue and steps Dr. Bregoli shall take to comply with the Integrity Requirements of this CCA. (This Stipulated Penalty shall begin to accrue 10 days after Dr. Bregoli receives notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-4 of this Section III.A.

B. Timely Written Requests for Extensions. Dr. Bregoli may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CCA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Dr. Bregoli fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Dr. Bregoli receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Dr. Bregoli has failed to comply with any of the obligations described in Section III.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Dr. Bregoli of: (a) Dr. Bregoli's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after receipt of the Demand Letter, Dr. Bregoli shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section III.E. In the event Dr. Bregoli elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Dr. Bregoli cures,

to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CCA and shall be grounds for exclusion under Section III.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section II.F.

4. *Independence from Material Breach Determination.* Except as set forth in Section III.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Dr. Bregoli has materially breached this CCA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section III.D, below.

D. Exclusion for Material Breach of this CCA.

1. *Definition of Material Breach.* A material breach of this CCA means:

- a. a failure by Dr. Bregoli to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section II.C;
- b. a repeated or flagrant violation of the obligations under this CCA, including, but not limited to, the obligations addressed in Section III.A; or
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section III.C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CCA by Dr. Bregoli constitutes an independent basis for Dr. Bregoli's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Dr. Bregoli has materially breached this CCA and that exclusion is the appropriate remedy, OIG shall notify Dr. Bregoli of: (a) Dr. Bregoli's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Dr. Bregoli shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. Dr. Bregoli is in compliance with the requirements of the CCA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Dr. Bregoli has begun to take action to cure the material breach; (ii) Dr. Bregoli is pursuing such action with due diligence; and (iii) Dr. Bregoli has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Dr. Bregoli fails to satisfy the requirements of Section III.D.3, OIG may exclude Dr. Bregoli from participation in the Federal health care programs. OIG shall notify Dr. Bregoli in writing of its determination to exclude him (this letter shall be referred to as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section III.E, below, the exclusion shall go into effect 30 days after the date of Dr. Bregoli's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Dr. Bregoli may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution.

1. *Review Rights.* Upon OIG's delivery to Dr. Bregoli of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CCA, Dr. Bregoli shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. §1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CCA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CCA shall be: (a) whether Dr. Bregoli

was in full and timely compliance with the requirements of this CCA for which OIG demands payment; and (b) the period of noncompliance. Dr. Bregoli shall have the burden of proving his full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CCA and orders Dr. Bregoli to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Dr. Bregoli requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CCA shall be:

- a. whether Dr. Bregoli was in material breach of this CCA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Dr. Bregoli had begun to take action to cure the material breach within that period; (ii) Dr. Bregoli has pursued and is pursuing such action with due diligence; and (iii) Dr. Bregoli provided to OIG within that period a reasonable timetable for curing the material breach and Dr. Bregoli has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Dr. Bregoli, only after a DAB decision in favor of OIG. Dr. Bregoli's election of his contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Dr. Bregoli upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Dr. Bregoli may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Dr. Bregoli shall waive his right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Dr. Bregoli, he shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CCA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CCA.

IV. EFFECTIVE AND BINDING AGREEMENT

Dr. Bregoli and OIG agree as follows:

A. This CCA shall be binding on the successors, assigns, and transferees of Dr. Bregoli;

B. This CCA shall become final and binding on the date the final signature is obtained on the CCA;

C. Any modifications to this CCA shall be made with the prior written consent of the parties to this CCA;

D. OIG may agree to a suspension of Dr. Bregoli's obligations under this CCA in the event of Dr. Bregoli's cessation of participation in Federal health care programs. If Dr. Bregoli withdraws from participation in Federal health care programs and is relieved of its CCA obligations by OIG, Dr. Bregoli shall notify OIG at least 30 days in advance of Dr. Bregoli's intent to reapply as a participating provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CCA should be reactivated or modified.

E. The undersigned Dr. Bregoli signatories represent and warrant that they are authorized to execute this CCA. The undersigned OIG signatory represents that he is signing this CCA in his official capacity and that he is authorized to execute this CCA.

ON BEHALF OF DR. BREGOLI


Arthur J. Bregoli, Jr., M.D.

DATE

Michael D. Kendall, Esq.
Counsel for Dr. Bregoli

DATE

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**




Lewis Morris
Chief Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

12/30/04


DATE

ON BEHALF OF DR. BREGOLI



Arthur J. Bregoli, Jr., M.D.


12/30/04
DATE 1/4/05



Michael D. Kendall, Esq.
Counsel for Dr. Bregoli

12/30/04 -
DATE 1/3/05

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**



Lewis Morris
Chief Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

12/30/04
DATE

Appendix A

DECLARATION

The declarant is Dr. Bregoli, the owner and manager of the medical practice known as Arthur R. Bregoli, Jr., M.D., P.C., (hereafter, the "Bregoli Practice") and he has personal knowledge of the facts stated herein. The following describes the compliance program (Program) currently in place at the Bregoli Practice.

1. The annual budget for the Program is attached hereto as Exhibit 1 and Dr. Bregoli shall sustain, at a minimum, the levels of funding reflected therein for three years subsequent to the Effective Date.

2. Under the Program, Dr. Bregoli serves as the Compliance Contact who is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with Federal health care program requirements. Dr. Bregoli also is responsible for monitoring the day-to-day compliance activities of the Bregoli Practice.

3. Dr. Bregoli has in place a Code of Conduct that includes: (a) Dr. Bregoli's commitment to full compliance with all Federal health care program requirements, including his commitment to prepare and submit accurate claims consistent with such requirements; (b) Dr. Bregoli's requirement that all of his personnel are expected to comply with all Federal health care program requirements and with the Policies and Procedures described in Paragraph 4 below; (c) the requirement that all of Dr. Bregoli's personnel are expected to report to the Compliance Officer or other appropriate individual designated by Dr. Bregoli suspected violations of any Federal health care program requirements or of Dr. Bregoli's own Policies and Procedures; (d) the possible consequences to both Dr. Bregoli and his personnel of failure to comply with Federal health care program requirements and with Dr. Bregoli's own Policies and Procedures and the failure to report such noncompliance; and (e) the right of Dr. Bregoli's personnel to use the Disclosure Program described in Paragraph 7 below and Dr. Bregoli's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures. Dr. Bregoli, and each co-owner, officer, director, and employee is required to certify in writing that he or she has received, read, understood, and will abide by the Code of Conduct.

4. Dr. Bregoli has in place Policies and Procedures regarding the operation of the Program and Dr. Bregoli's compliance with Federal health care program requirements. The Policies and Procedures are distributed to all relevant personnel. At least annually (and more frequently, if appropriate), Dr. Bregoli reviews and updates as necessary his

Policies and Procedures and, if revisions are made, distributes the relevant portions of any revised Policies and Procedures to all personnel whose job functions relate to the revised Policies and Procedures.

5. Dr. Bregoli has in place an annual training program that requires Dr. Bregoli and all co-owners, officers, directors, and employees to attend at least one hour of annual compliance training that addresses Dr. Bregoli's Code of Conduct and the operation of the Program. Dr. Bregoli's annual training program also requires additional hours of training for Dr. Bregoli and all co-owners, officers, directors, and employees who provide patient care items or services or who perform billing, coding, or claims submission functions. Such additional training addresses: (a) the Federal health care program requirements regarding the accurate coding and submission of claims; (b) policies, procedures, and other requirements applicable to the documentation of medical records; (c) the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate; (d) applicable reimbursement statutes, regulations, and program requirements and directives; (e) the legal sanctions for violations of Federal health care program requirements; and (f) examples of proper and improper coding and claims submission practices. Dr. Bregoli maintains written or electronic records that identify the type of annual training provided, the date(s) of the training, and the attendees. Persons providing the training are knowledgeable about the subject area. Dr. Bregoli reviews the training content on an annual basis and, as appropriate, updates the training to reflect changes in Federal health care program requirements and/or any issues discovered during the internal audits described in Paragraph 6 below.

Dr. Bregoli represents that Medical Data Services and its owners and employees (collectively "MDS") is a contractor retained by Dr. Bregoli to perform limited billing functions on behalf of Dr. Bregoli. Dr. Bregoli further represents that MDS does not perform any discretionary functions with regard to the coding of claims for services provided by Dr. Bregoli, that MDS does not receive any patient charts from Dr. Bregoli, and that MDS merely receives and utilizes coding information provided by Dr. Bregoli in preparing bills to be submitted for services. Dr. Bregoli represents that he is unable to compel MDS or any of its owners or employees to sign the Code of Conduct referenced above in Paragraph 3 or to attend the training referenced in this Paragraph 5. However, Dr. Bregoli agrees to provide MDS with a copy of his Code of Conduct within 90 days after the Effective Date and to strongly encourage MDS to obtain annual training covering the topics identified in this Paragraph 5 on an annual basis. Dr. Bregoli shall report to the OIG about the training, if any, received by MDS in each Annual Report.

6. Dr. Bregoli has retained an auditor who performs at least annual reviews to monitor Dr. Bregoli's compliance with Federal health care program requirements, including Evaluation and Management Coding, and coding related to Patient Day of

Discharge (including the coding of claims by both Dr. Bregoli and by his nurse practitioners.)

7. Dr. Bregoli maintains a Disclosure Program that includes a mechanism to enable individuals to disclose, to Dr. Bregoli or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Dr. Bregoli's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Dr. Bregoli publicizes the existence of the disclosure mechanism to all personnel.

The Disclosure Program emphasizes a nonretribution, nonretaliation policy and includes a reporting mechanism for anonymous communications for which appropriate confidentiality is maintained. Each disclosure is reviewed by the Compliance Officer, who either investigates the disclosure or refers the disclosure to the relevant department or manager for follow up and any appropriate corrective action.

The Compliance Officer (or designee) maintains a disclosure log, which includes a record and summary of each disclosure received (whether anonymous or not), the status of Dr. Bregoli's internal review of the allegations, and any corrective action taken in response to the internal review.

8. Dr. Bregoli has in place a policy and procedure for screening all prospective owners, officers, directors, employees, contractors, and agents to ensure that they are not Ineligible Persons¹ by: (a) requiring such persons to disclose whether they are an Ineligible Person; and (b) appropriately querying the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://eppls.arnet.gov>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>) (these lists shall hereinafter be referred to as the "Exclusion Lists"). Dr. Bregoli also performs annual screening of his current co-owners, officers, directors, employees, contractors, and agents against the Exclusion Lists and requires all owners, officers, directors, employees, contractors, and agents to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

¹ An "Ineligible Person" is an individual or entity who: (i) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or (ii) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

Dr. Bregoli also has a policy in place that, if he has actual notice that a co-owner, officer, director, employee, contractor, or agent has become an Ineligible Person, Dr. Bregoli will remove such person from responsibility for, or involvement with, Dr. Bregoli's business operations related to the Federal health care programs and will remove such person from any position for which the person's compensation or items or services furnished, ordered, or prescribed by the person are paid in whole or in part, directly or indirectly, by Federal health care programs or otherwise with Federal funds, at least until such time as the person is reinstated into participation in the Federal health care programs. (Nothing in this Declaration affects the responsibility of Dr. Bregoli to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded individuals or Dr. Bregoli's liability for overpayments received by Dr. Bregoli as a result of billing any Federal health care program for such items or services.)

The undersigned signatory represents and warrants that he is authorized to execute this declaration on behalf of Dr. Bregoli.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this ____ day of _____.

Arthur J. Bregoli, Jr., M.D.

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date: _____
 Contractor Deposit Control # _____ Date of Deposit: _____
 Contractor Contact Name: _____ Phone # _____
 Contractor Address: _____
 Contractor Fax: _____

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIER NAME _____
 ADDRESS _____
 PROVIDER/PHYSICIAN/SUPPLIER # _____ CHECK NUMBER# _____
 CONTACT PERSON: _____ PHONE # _____ AMOUNT OF CHECK
 \$ _____ CHECK DATE _____

REFUND INFORMATION

For each Claim, provide the following:

Patient Name _____ HIC # _____
 Medicare Claim Number _____ Claim Amount Refunded \$ _____
 Reason Code for Claim Adjustment: _____ (Select reason code from list below. Use one reason per claim)

(Please list all claim numbers involved. Attach separate sheet, if necessary)

Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment: _____

For Institutional Facilities Only:

Cost Report Year(s) _____
 (If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

For OIG Reporting Requirements:

Do you have a Corporate Integrity Agreement with OIG? Yes No

Reason Codes:Billing/Clerical Error

01 - Corrected Date of Service
 02 - Duplicate
 03 - Corrected CPT Code
 04 - Not Our Patient(s)
 05 - Modifier Added/Removed
 06 - Billed in Error
 07 - Corrected CPT Code

MSP/Other Payer Involvement

08 - MSP Group Health Plan Insurance
 09 - MSP No Fault Insurance
 10 - MSP Liability Insurance
 11 - MSP, Workers Comp.(Including
 Black Lung
 12 - Veterans Administration

Miscellaneous

13 - Insufficient Documentation
 14 - Patient Enrolled in an HMO
 15 - Services Not Rendered
 16 - Medical Necessity
 17 - Other (Please Specify)